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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,368	03/25/2004	Andreas Bergmann	2582.024A	4724

7590 11/21/2007  
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ALBANY, NY 12203-5160

EXAMINER
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MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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11/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/808,368

Applicant(s)

BERGMANN ET AL.

Examiner

Prema M. Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-7 have been canceled (11/5/07). New claims 8-10 are pending and under consideration in the instant application.
2. Receipt of applicant's arguments filed on 11/5/2007 is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 11/5/2007:
  - (i) the objection to the title of the invention;
  - (ii) the rejection of claims 1-5, 7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement;
  - (iii) the rejection of claims 1-5, 7 under 35 U.S.C. 112, first paragraph, for scope of enablement;
  - (iv) the rejection of claims 1-5, 7, under 35 U.S.C. 112, second paragraph; and
  - (v) the rejection of claims 1-2, 5, under 35 U.S.C. 102(b) as being anticipated by Lubbesmeyer et al (1988).
4. Applicants arguments filed on 11/5/2007 have been fully considered and were persuasive. The new issue is stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6a. Claims 8-10 are rejected under 35 U.S.C. 103(a) as unpatentable over Lubbesmeyer et al (1988) in view of U.S. Patent No. 5,639,617 ('617 patent) and DRG Instruments GmbH.

Lubbesmeyer et al teach detection of sepsis in sheep by an immunoassay of plasma in the sheep in which ANF is detected (see abstract; Figure 1, page R568). The concentration of ANF was 13-fold higher within 2 hours after endotoxin administration (abstract, page R568, column 2, second para).

US Patent No. '617 teaches a method for the detection of sepsis by obtaining serum from the individual and using an antibody selective to pro-calcitonin to determine the level of pro-calcitonin relative to healthy individuals (see abstract; column 3, lines 27-60; column 6, Example 1, lines 41-65; column 8, lines 30-41).

DRG Instruments GmbH (see Applicants specification, page 18, lines 27-30; page 19, lines 1-9) teaches a kit for determining the level of pro-ANF and other pro-hormones.

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Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lubbesmeyer in view of the '617 patent by using antibodies to pro-ANF as described by DRG Instruments GmbH because the '617 patent teaches that antibodies to the pro-hormone are selective and when used in determining the levels of pro-hormone increase are a clear and valuable way for detection of sepsis. Furthermore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lubbesmeyer in view of the '617 patent by using in the claimed method, antibodies to pro-ANF as well as antibodies to procalcitonin for the detection of sepsis, because the '617 patent teaches that determining the level of procalcitonin is indicative of the detection of sepsis (for diagnosis and assessing the progression of sepsis).

### ***Conclusion***

No claim is allowed.

Claims 8-10 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/  
Primary Examiner  
Art Unit 1646